



FDA Statement

FOR IMMEDIATE RELEASE

Statement
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Bausch & Lomb Global Recall of ReNu with MoistureLoc Contact Lens Cleaning Solution

On Thursday, May 11, 2006 a team from Bausch & Lomb met with Food & Drug Administration (FDA) officials to share information resulting from the company's internal investigation into cases of *Fusarium* keratitis associated with ReNu with MoistureLoc.

Bausch & Lomb has proposed that unique characteristics of the formulation of the ReNu with MoistureLoc product in certain unusual circumstances can increase the risk of *Fusarium* infection.

Based on this scientific and epidemiological data suggesting that ReNu with MoistureLoc may increase susceptibility to *Fusarium*, Bausch & Lomb has decided to permanently remove the ReNu with MoistureLoc product worldwide. FDA supports this decision. To date, data available do not indicate a problem with ReNu MultiPlus or ReNu Multi-Purpose or generic brands of this contact lens cleaning solution.

While FDA is still concluding its scientific evaluations and expects additional information to be submitted by the sponsor, at this time we recognize that Bausch & Lomb has proposed the formulation as the potential root cause of the increased relative risk of *Fusarium* keratitis associated with use of the ReNu with MoistureLoc product. FDA will continue to review cultures and epidemiological data and if there is new information that adds to or changes our current understanding, we will act on it in a timely and appropriate manner.

As part of the joint Center for Disease Control & Prevention (CDC) and FDA investigation, field officers have been inspecting the Bausch & Lomb plant and facilities in Greenville, SC since March 22, 2006. While the plant inspection is being finalized, there is still some additional testing to be completed. The agency plans to issue observations from the inspections imminently.

ReNu with MoistureLoc contact lens solution, manufactured in the Greenville, SC plant, was voluntarily withdrawn from the market in the United States on April 13, 2006. To date, a majority of the confirmed *Fusarium* cases have been associated with the ReNu with MoistureLoc. Our interest in the MoistureLoc product has been based on the disproportionate number of cases of *Fusarium* keratitis associated with ReNu with Moisture Loc compared to the overall product market share. Based on CDC reports, the number of cases involving various contact lens solutions other than MoistureLoc has remained consistent throughout our investigation, and not disproportionate from the routine incidence of this infection in the population.

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